UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' BRIEF IN SUPPORT OF MOTIONS IN LIMINE

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1. **Defendants cannot assert that it is not appropriate to perform a retrospective analysis of their conduct or the consequences, including for example the resulting adulteration of the contaminated API and VCDs.**

Defense witnesses including certain experts have opined/suggested that it is not legitimate to evaluate the Defendants' conduct or to determine whether the contaminated drugs were contaminated retrospectively. Of course, that is exactly what happens at a trial, and any suggestion that retrospective analysis is not legitimate would be false and confusing. The Court recognized this is in ruling on the *Daubert* motions on liability. (ECF 2581 (stating: "Williams states that the contaminated VCDs could not have been 'adulterated' before the FDA became aware of the contamination in the summer of 2018. **This is sophistry**, which attempts to avoid a retrospective characterization of Teva's finished dose products as 'adulterated' from the start of the nitrosamine contamination." (emphasis added)).

2. **Defendants cannot defend their conduct by pointing to lack of knowledge or action by the FDA prior to ZHP's disclosure of the contamination in June 2018, or blame or point the finger at the FDA in any way as a defense or excuse for their conduct.**

Defendants' witnesses have defended their conduct by arguing that the FDA also did not identify the risk or occurrence of the contamination from the manufacturing processes at issue until disclosure by ZHP. Their purpose is to argue that the contamination was the FDA's fault, or unavoidable, because the FDA did not prevent it. First, this argument is a red herring intended to deflect from the fact

that the contamination of the valsartan API and finished dose with genotoxic probable human carcinogens NDMA and NDEA was always precluded by regulation. See: FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) (" [T]here are some compounds containing certain structural groups (aflatoxin-like-, N-nitroso-, and azoxy-structures) that have extremely high carcinogenic potency and are excluded from the threshold approach," and per Section 4A: "**Every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing**.") (Ex. 2, p. 7, 8) (emphasis added)).[1] In this connection, the USP also required ZHP to develop and implement whatever analytical methods were needed to identify and prevent unknown impurities from the new manufacturing processes created by ZHP. (Ex. 8, p. 4; Ex. 9, p. 9; Ex. 10, p. 2).

In addition, this tactic should be precluded since the FDA's action or inaction is not a justification for Defendants' failings, and even if tangentially relevant, it would mislead and confuse the jury, and severely prejudice Plaintiffs. F.R.E. 401, 403. The FDA explicitly rejected ZHP's attempt to shift or evade blame, stating in the Warning Letter: "Your response states that predicting NDMA formation during

[1] All exhibits are attached to Adam M. Slater's Certification in support of Plaintiffs' motions in limine.

the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree. **We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce**." (emphasis added)) (ZHP01344162) (Ex. 6)).

The Defendants also admitted that they were responsible for the quality of the drugs they manufactured and sold. (Jun Du 5/28/21 Dep. Tr. 250:14-17 (agreeing "that ZHP is responsible for the quality of drugs that ZHP produces") (Ex. 3); Eric Gu 4/6/21 Dep. Tr., 360:8-374:12 (confirming "ZHP was responsible for the quality of the valsartan that it manufactured.") (Ex. 4); Min Li 4/21/21 Dep. Tr. 433:21-434:7 (same) (Ex. 5); Dawn Chitty 5/13/21 Dep. Tr. 21:11 agreeing that Torrent is "required to make sure [its drugs meet] current specifications and is compliant with the agreed-upon standards before it leaves the plant; Dep. Tr. 338:8-17 agreeing that "as a finished dose manufacturer" it is Torrent's "job to test [its] own product to determine whether or not it meets regulatory standards.") (Ex. 55); Sushil Jaiswal Dep. Tr. 152:17-153:8 stating that Torrent's quality department is responsible for qualifying and supervising API suppliers) (Ex. 56); Barreto Dep. Vol. I. at 62:5-63:6 ("So Teva's responsibility for the finished product includes the API, it includes the excipients, and it includes ensuring that the manufacturing process and the testing activities and anything that is associated with ensuring the

safety, quality, and efficacy and purity of that product that those – those expectation are set; not just for the API but for everything.") (Ex. 57); Lyons Dep. at 285:3-12 ("Q: In fact, as the – in the US, at least, as the ANDA holder for a finished dose product, Teva bears responsibility for the product that it sells in the US market, including the materials therein, correct? A: Yes, that's correct. Q: That would include API, correct? A: Yes, it does include API.") (Ex. 58); Williams 2/17/22 Dep. at 40:7-15 ("Q: Do you agree that a drug-product manufacturer is ultimately responsible for the API that it incorporates into its finished-dose product? A: Yes, I think that's generally a fair statement, Mr. Stanoch. Q: Yeah. So Teva is ultimately responsible for the valsartan API that was in its finished-dose valsartan product, correct? A: Yes, I think I can agree with that.") (Ex. 59)).

The cGMP violations were not discovered by the FDA because ZHP unilaterally changed the manufacturing processes, and the FDA was not in a position to discover the issues. (FDA, *FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues* (Jan. 25, 2019) ("**It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice (CGMP) inspection. Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise**.") (Ex. 7)).

And the DMFs for both processes at issue falsely represented that no genotoxic impurities were created by the new manufacturing process. "there is not any high potency genotoxic group, such as, aflatoxin-like-, N-nitroso-, and azoxy-compound has been included in these impurities." (HUAHAI-US00007898-7899 (Ex. 16); PRINSTON00080118-80119 (Ex. 17)).

Allowing the Defendants to blame the FDA for not doing what was required of them, or as an excuse, would create an off-ramp to a mini-trial on the role and information available to the FDA. This would waste trial time and improperly distract and mislead the jury from focusing on Defendants' manufacture and sale of genotoxin contaminated API and VCDs as if it was the approved, USP/Orange Book compliant valsartan - which required a recall as soon as it was disclosed. This should not be permitted.

3. Defendants cannot blame third-parties, including prescribing physicians, the FDA, or others, for the damages at issue.

Defendants pled affirmative defenses vaguely blaming "third-parties" for the damages here. (ECF 2549 at 61, 62-63; ECF 2548 at 112-113, 115; ECF 2547 at 306). Defendants should not be permitted to point to or blame any third-parties for their wrongdoing. Defendants' plan to point the finger at the FDA has been addressed above. Though Defendants stipulated that they will not seek to blame prescribing physicians, they curiously would not agree to stipulate that the prescribers cannot be deemed superseding/intervening causes—which are tort

concepts. Since the role of the prescribers, prescribing valsartan, was always known and foreseen they cannot be superseding/intervening causes by definition. *Bouriez v. Carnegie Mellon Univ.*, 585 F.3d 765, 773 (3d Cir. 2009); *Komlodi v. Picciano*, 89 A.3d 1234, 1252 (2014). Defendants have refused to disclose what other third-parties they were referencing, and they should be precluded from blaming any. *See* Fed. R. Evid. 401, 403.

4. **Defendants cannot assert that the FDA statement advising patients not to discontinue their use of the VCDs until they could obtain a prescription for a replacement medication or treatment meant that the FDA did not believe that there was an unacceptable health risk due to the contamination of the VCDs.**

The FDA advised patients not to discontinue their VCDs (in most cases already purchased) until promptly seeing their doctors and having a replacement treatment prescribed. (Ex. 18, p. 1). This was obviously based on a weighing of the immediate risk of heart attacks and strokes from withholding medication, against the longer term risk of cancer. This is the definition of being between a rock and a hard place. All of the contaminated valsartan at issue was recalled and the FDA never stated that the carcinogenic risk was acceptable, that is the bottom line. **Defendants confirmed the bottom line: the recall was due to the "unacceptable carcinogenic risk to the intended patient population**." (SOLCO00024231 (Ex. 49); SOLCO00024226 (Ex. 50)). Because the FDA's short term advice on patients' transition to safe treatments has absolutely no probative value, and would only be

used to confuse and mislead the jury, it should be excluded. F.R.E 401, 403.

For the same reason, the Defendants should also be precluded from introducing evidence that SummaCare and Emblem followed the FDA guidance and instructed their members to continue taking their VCDs in the immediate short-term following the recalls until they spoke to their doctors about having replacement medication prescribed. That advice was appropriate and is not probative of a lack of risk—much to the contrary, but there is no point to injecting it into the trial and risking jury confusion.

5. **The FDA information statements regarding the valsartan and other sartans' contamination should not be referenced, or used to defend or deflect liability. For example, ZHP cannot assert that they excuse ZHP's violations of cGMPS since one of the statements explicitly notes ZHP's violations and the Warning Letter, and they do not excuse the sale of the contaminated VCDs, all of which were recalled due to the contamination.**

Defendants, in particular ZHP, have focused their experts on two update statements from the FDA that generally discuss the nitrosamine contamination of valsartan, and other drugs, and cherry pick statements therein that they present out of context as if the FDA exculpated them for the contamination or was partially at fault. (Ex. 7; Ex. 18). For example, Dr. Afnan's report (in a part precluded by this Court's *Daubert* ruling) states, "According to the January 2019 statement, the FDA's 'investigation into ZHP's process identified that a change made to the manufacturing process likely led to this impurity, and that the impurity went undetected by global regulators, including the FDA, for a period of time. **Before we undertook this**

analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing process.'" (Afnan R., p. 49 (Ex. 19)). These are broad, general informational statements that did not exculpate any manufacturer. On the other hand, the statement issued on January 25, 2019 directly **criticized ZHP**:

> **We've placed a ZHP facility on import alert to stop all its API and finished drugs made using ZHP's API from legally entering the U.S. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control and cross contamination from one manufacturing process line to another. It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice (CGMP) inspection**. Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise.

FDA, *FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues* (Jan. 25, 2019) (Ex. 7). Of course, as set forth above the lack of understanding by regulators was because ZHP developed the manufacturing processes itself and misrepresented in the DMFs that the resulting product met the approved specifications and that no genotoxic impurities were created.

Allowing Defendants to point to and spin these general informational statements, and having the Parties go back and forth on the parts they want to highlight, will waste trial time and could easily confuse and mislead the jury into

thinking the FDA exculpated Defendants or accepted some of the blame—which it did not. Moreover, the expansive discussion of the scope of the problem across the industry is excluded because the Parties have agreed that settlements with other manufacturers should not be referenced—an issue also addressed in MIL 6 directly below. These statements should be excluded.

6. **Defendants cannot assert that there was an industry-wide problem, or that industry standards did not require them to identify and control all genotoxic impurities from their manufacturing processes.**

Defendants should not be permitted to turn the trial into a distracting evaluation of the industry as a whole—it is their conduct that is at issue in this trial. FRE 401, 403. Defense witnesses, in particular from ZHP, testified that this was an industry wide problem as an argument to evade liability. (*See, e.g.*, Min Li 4/21/2021 Dep. Tr. 399:18-23 (Ex. 5)). There would be no benefit to telling the jury that other manufacturers had similar but in some cases not identical problems, and that would pull in the need to waste trial time explaining and putting that broad swath into context.

As set forth above, the FDA unequivocally rejected ZHP's effort to hide behind this being a problem across the industry, and purported but not defined industry practices or standards: "**We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce**." (ZHP01344162 (Ex. 6)). Also

as set forth above, this was admitted by Defendants' corporate representatives. Defendants should not be permitted to shift or duck blame by pointing at the industry as a whole. And consistent with MIL Stipulation 8, the Parties cannot inform the jury that other manufacturers have settled, and this issue falls under that umbrella as well, since that would involve explaining what they did. There is no benefit to injecting the conduct of the "industry."

Moreover, this would be an impermissible version of "everyone else was doing it," as a justification for Defendants' own failings. *Royal Bahamian Ass'n, Inc. v. QBE Ins. Corp.*, 744 F. Supp. 2d 1297, 1303 (S.D. Fla. 2010) ("As our own Eleventh Circuit has held about the, "But everyone else was doing it!" defense, without inquiring as to what a defendant in a civil case would do if everyone else were jumping off a bridge, we recognize that precedent squarely precludes his claim.") (internal quotations omitted) (citing to *O'Rourke v. Hayes*, 378 F.3d 1201, 1210 (11th Cir. 2004)); *United States v. Sittenfeld*, 1:20-CR-142, 2022 WL 2192955, at *5 (S.D. Ohio June 17, 2022); *see also United States v. Vasilakos*, 508 F.3d 401, 409 (6th Cir. 2007) (affirming exclusion of evidence that "others did it too" as irrelevant to defendant's guilt); *LaCrosse v. Commodity Futures Trading Comm'n*, 137 F.3d 925, 933 (7th Cir. 1998) (rejecting defense that "everyone else was doing it" and related theory that this misconduct by others "somehow mitigated his illegal behavior").

The trial should focus on the conduct of the trial Defendants, not other manufacturers or vague industry conduct or practice. The regulations and SOPs are clear and that is the measure of their conduct.

7. **ZHP Defendants cannot disclose or rely on hearsay discussions with Jinsheng Lin, Ph.D, or other sources, to assert translation or interpretation of the July 27, 2017 email that differs from 30(b)(6) testimony of Min Li, or ZHP's translation.**

Defendants have indicated that they intend to present the testimony of ZHP quality assurance head Jucai Ge at trial. Jucai Ge was a 30(b)(6) deponent and testified in her final deposition that she spoke with Jinsheng Lin, Ph.D., the author of the July 17, 2017 email, and that Dr. Lin told her that the email does not mean what it says—based on his private, undisclosed "intention." Specifically,

> I have to admit that this e-mail is poorly written and ambiguous, to be the least. However, your interpretation is oversimplified. You could not just take this sentence out of the context and come up with this interpretation, which did not reflect **the true intention of Dr. Lin**, **which was confirmed through my communication with him.**
>
> * * *
>
> Q. When Jinsheng Lin said in his July 27, 2017 e-mail that there was NDMA that occurs in valsartan when quenched with sodium nitrite, that was an accurate statement, correct?
>
> A. That's incorrect. I don't think your interpretation was a correct reflection of **the intention of the author**.
>
> Q. That's what the words on the page say, correct?

> A. That's incorrect. That -- as I stated in my prior testimony, this e-mail was poorly written and complicated, as you could see here, **even though that was the words that said so on this page**. . .

(Jucai Ge 5/26/2022 Dep. Tr. 79:7-16, 83:7-84:7 (emphasis added) (Ex. 46)).

This testimony is intended to allow defense counsel to argue that the email should not be believed—despite 30(b)(6) witness Min Li clearly testifying to what the email said (Min Li 4/20/2021 Dep. Tr. 82:11-12, 87:19-88:7, 88:13-89:18 (Ex. 24)), and the translation presented and used by ZHP saying the same thing (Ex. 47)—**that there was NDMA in valsartan, caused by the sodium nitrite quenching**.

Aside from the utter lack of credibility, and conflict with 30(b)(6) testimony, the hearsay testimony of Jucai Ge as to what Jinsheng Lin told her, is inadmissible since ZHP cannot affirmatively offer the statement for the truth of what was stated, as it is not subject to any hearsay exception. Jucai Ge's designation as a 30(b)(6) corporate representative does not allow the impermissible hearsay to be admitted. *See Chevron TCI, Inc. v. Capitol House Hotel Manager, LLC*, 541 F. Supp. 3d 687, 694 (M.D. La. 2021) (holding that "a corporate representative may not testify to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.') (quoting *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 435 (5th Cir. 2006)) (citing *Deutsche Shell Tanker Gesellschaft mbH v. Placid Refining Co.*, 993 F.2d 466, 473 n. 29 (5th Cir. 1993)); *Diamond Offshore Co. v. Survival Sys. Int'l, Inc.*, 902 F. Supp. 2d 912, 932

(S.D. Tex. 2012) (holding: "The statements made on information and belief based on Mark Beatty's conversations with Captain Beatty are hearsay and cannot be transformed into admissible evidence simply because Mark Beatty is a corporate representative."). Thus, these discussions and Jucai Ge's self-serving rendition of Jinsheng Lin's undisclosed intention cannot be inserted into the trial.

8. **Defendants cannot assert or argue that NDMA and NDEA are not, and were not known to be at all relevant times, genotoxic, probable human carcinogens.**

The issue in this trial is the unacceptable risk posed by the NDMA and NDEA contamination, which required a worldwide recall, and the economic consequences. That unacceptable risk is a direct result of the status of NDMA and NDEA as genotoxic, probable human carcinogens. These classifications were established in the scientific literature and controlling regulatory guidances long before ZHP developed and implemented its ill-fated API manufacturing processes. This includes:

- "N-nitrosiethylamine should be regarded for practical purposes as if it were carcinogenic to humans," and "N-nitrosodimethylamine should be regarded for practical purposes as if it were carcinogenic to humans." IARC, *Some N-Nitroso Compounds*, p. 107, 152 (1978) (Ex. 20); *see also* IARC, *Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42*, p. 42 (1987) (clarifying that NDMA and NDEA are probable human carcinogens) (Ex. 21).

- "Some structural groups were identified to be of such high potency that intakes even below the TTC would be associated with a high probability of a significant carcinogenic risk (Cheeseman et al. 1999, Kroes et al. 2004). This group of high potency genotoxic carcinogens comprises aflatoxin-like-, N-

nitroso-, and azoxy-compounds that have to be excluded from the TTC approach." EMEA, *Guideline on the Limits of Genotoxic Impurities*, p. 6 (2006) (Ex. 15).

- FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) ("[T]here are some compounds containing certain structural groups (aflatoxin-like-, N-nitroso-, and azoxy-structures) that have extremely high carcinogenic potency and are excluded from the threshold approach.") (Ex. 2)

ZHP's DMFs for the ZnCl2 and TEA with sodium nitrite quenching process cite and rely on the cited FDA and EMEA guidances as the source of authority where they explicitly misrepresented in the 2013 DMFs that there were no n-nitroso compounds in the API - a representation only made because it was known they were prohibited. HUAHAI-US00007898-7899 (Ex. 16); PRINSTON00080118-80119 (Ex. 17). ZHP's 30(b)(6) witnesses have repeatedly agreed: NDMA is "a **highly toxic impurity**… I agree that NDMA is a genotoxic impurity" (ZHP's Optimized Valsartan Patent (Ex. 22); Jucai Ge 5/27/22 Dep. Tr., 159:12-161:20, 173:13-14 (Ex. 23)); "NDMA is a probable human carcinogen, probable." (Eric Gu 4/6/2021 Dep. Tr. 66:15-16 (Ex. 4); Min Li 4/20/2021 Dep. Tr., 101:22-102:8 (confirming that "NDMA and NDEA are considered to be mutagenic/genotoxic impurities") (Ex. 24); Jun Du 5/27/21 Dep. Tr., 96:2-3 ("a probable human carcinogen") (Ex. 25); Hai Wang 3/10/21 Dep. Tr., 276:5-11, 321:16-22 (confirming that NDMA "has been classified as a probable human carcinogen as per International Agency for Research on Cancer classification") (Ex. 26)); "NDMA is a potent mutagenic carcinogen"

(Nudelman 4/8/21 Dep. at 170:18-20 ("mutagenecitiy is the toxicity of highest concern" and NDMA "is known to be a mutagenic substance" (Nudelman 4/8/21 Dep. at 82:12-83:4) (Ex. 60)). Defendants should be precluded from disputing these classifications.

9. General causation is not an element of the claims at issue, and is not an issue to be determined at trial.

During the Parties' meet-and-confer on the MILs, Defendants agreed that general causation is not an element of the claims at issue, and the jury will not be asked to decide general causation. This is because the question in this trial is the impact of the "unacceptable carcinogenic risk" posed by the NDMA and NDEA contamination, and the consequent economic impact, NOT whether the contaminated pills caused cancer to anyone.

Nonetheless, Defendants refused to stipulate to this point, as they have declared that they want to present extensive general causation evidence in an effort to demonstrate that the extent of contamination here was so minor that it could not have an economic impact. In doing so, they intend to try to prove to the jury that the amount of contamination was not sufficient to actually cause cancer. This is not a personal injury case where the jury will ever be asked if the contaminated pills caused cancer so injecting general causation will hopelessly burden, lengthen, and confuse the trial and severely prejudice Plaintiffs in proving the elements of the claims actually being tried.

Specifically, Defendants want to argue that the "dose" of NDMA and NDEA contaminating the valsartan was so small that it was not likely to cause cancer and thus did not impact the economic value of the pills—even though the risk required the recall. Along the same lines, Defendants consistently characterize the contamination of their VCDs as trace, small, and tiny, suggesting the amount of contamination was insufficient to have an economic impact or require the contaminated VCDs not be sold, or to be recalled—even though the risk required the recall. And Defendants have admitted that the contamination levels were many times the FDA limits. The test results show that the contamination levels were above the level of detection *and* above the acceptable daily limit set by the FDA. (*See*, *e.g.*, ZHP00079913 (Ex. 41); TORRENT-MDL2875-00133890 (Ex. 42); ZHP02563814 (Ex. 37); Min Li 4/21/21 Dep. Tr., 306:15-23, 472:12-476:19 (Ex. 5)).

Moreover, most to the point, Defendants admitted that if the contamination was known the products would not have been sold. (Eric Gu 4/6/21 Dep. Tr. 391:12-394:7, 395:10-397:10 (Ex. 4); Min Li 4/22/21 Dep. Tr., 696:3-697:4; 699:24-700:15 (Ex. 51)). **Defendants cannot use "dose" arguments to negate the regulatory reality that the amounts at issue precluded the sale of the products**. Injecting these arguments into the trial would be misleading by definition since we know the risk precluded the sale of the contaminated API and VCD's once disclosed. That is the issue.

This argument would also fly in the face of the regulatory guidances in place before and during the time that the contaminated API and VCDs were manufactured, which clearly stated that NDMA and NDEA/n-nitroso compounds were part of the category of highly toxic substances that were placed in their own category, known as the "cohort-of-concern." ICH, *M7* p. 10 (2013) (Ex. 1); EMEA, *Guideline on the Limits of Genotoxic Impurities*, p. 6 (2006) (Ex. 15); FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products*, p. 7-8 (2008) (Ex. 2). ZHP witnesses have admitted that these regulatory guidances were referenced and relied on by ZHP, including the 2008 FDA Guidance, and the 2007 EMEA Guidance, both of which were cited to in the relevant DMFs. (HUAHAI-US00007898-7899 (Ex. 16); PRINSTON00080118-80119 (Ex. 17)). **The import of this categorization is that any exposure was deemed to present a significant and unacceptable carcinogenic risk.** FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products*, p. 7-8 (2008) (stating: "**every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing**") (Ex. 2); EMEA, *Guideline on the Limits of Genotoxic Impurities*, p. 6 (2006) (identifying N-nitroso compounds as "structural groups were identified to be of such high potency that intakes even below the TTC would be associated with a high probability of a significant carcinogenic risk") (Ex. 15).

The type of arguments Plaintiffs understand Defendants to want to make are illustrated in the opening statement of ZHP's trial counsel in a Johnson & Johnson baby powder trial that opened this past week in Miami. For example: if this common product caused this type of cancer, "where is the epidemic of primary peritoneal cancer?", "the science doesn't support it, that talc is a risk factor for ovarian cancer or primary peritoneal cancer,", "asbestos is everywhere. We are all exposed to asbestos," and pointing to the FDA's risk estimates as a "worst case scenario estimate." (Ex. 61, 545:14-18, 550:9-12, 567:5-10, 567:13-568:3). The big difference of course is that trial is a wrongful death case based on the claim that the product caused the cancer, whereas in this case proof that anybody developed cancer due in whole or part to the contaminated pills is not at issue. So those types of arguments have no place in this trial. And this is not a matter of degree - if these types of general causation arguments are let in at all, that puts the entire issue in play, requiring the testimony of many witnesses, and a much longer trial - which will thoroughly mislead and confuse the jury since proof of general causation is not an element in the trial.

Aside from trying to inject the confusion of causation—not an element in the trial—Defendants hope to re-litigate the FDA's decisions to require the recall, notwithstanding their own statements that the contamination presented an "unacceptable carcinogenic risk," claiming there was no real risk that cancer would

occur, and even that no patient using the contaminated pills developed cancer. But the propriety of the recall mandated by the FDA is not at issue in this trial, and actual causation of cancer is not the issue to be decided in this trial. Evidence and arguments on those points will result in a trial within a trial about the justifications or purported lack thereof in support of the FDA's required recall. Plaintiffs would then be forced to point to the significant scientific literature and data confirming general causation, such as the Gomm study demonstrating that the contaminated VCDs caused a statistically significant increased risk for liver cancer, and concluding that the recall was necessary due to the cancer risk. (Ex. 43). The back and forth and numerous experts who would inevitably testify on general causation related issues would significantly lengthen the trial, create an irrelevant mini-trial on an issue not an element of the claims, and completely distract and confuse the jury. This is exactly the type of prolonged general/specific causation arguments and evidence that the Court sought to avoid when it selected TPP economic loss subclasses for trial. The establishment of the risk requiring the recall is all that is necessary, and that cannot be disputed.

10. Defendants cannot reference or assert the Valisure Citizen Petition, in any way, including but not limited to with regard to Dr. Najafi, nor can they use the Valisure Citizen Petition to assert that brand diovan contained NDMA or NDEA.

Many of the reasons why this Court should exclude this evidence (especially as it relates to Dr. Najafi) were delineated in Plaintiffs' Motion to Quash the Valisure

Subpoena (ECF 2228), which was granted (ECF 2476). Any information related to the hearsay petition from a non-party, non-expert is inadmissible since no hearsay exception applies, and of absolutely no probative value to this case (or to Dr. Najafi's expert testimony), making its inclusion in any such trial confusing, misleading, and highly prejudicial. F.R.E. 401, 403.

Defendants' focus is on specific references in the Valisure petition suggesting that Valisure's testing of branded RLDs (Diovan and Exforge) indicated the presence of NDMA. However, there has been no reliability foundation established whatsoever in this litigation which would permit such highly prejudicial hearsay evidence. Were this foundational issue not enough, there is every reason to reject any such assertion. This is because Health Canada tested and confirmed that Diovan and Exforge did not contain nitrosamines. (Ex. 52). Moreover, on December 5, 2022, the FDA issued an untitled letter to Valisure, delineating a host of deficiencies that were observed by FDA inspectors related to their NDMA testing, including observations that its methods for such testing were flawed, that it did not adequately address OOS testing results, that it used instrumentation that did not meet established specifications, and that it failed to exercise appropriate controls. (Ex. 53). This would be a tedious, tertiary sideshow ending nowhere because even Defendants cannot point to any evidence that Diovan or Exforge had NDMA (indeed, they have continuously remained on the market to this day). Valisure should not be mentioned.

See Fed. R. Evid. 401, 403.

11. Defendants cannot argue that the specifications for the valsartan API and VCD's permitted the NDMA and NDEA contamination/that the specifications did not prohibit the NDMA and NDEA contamination.

Defendants' DMFs and ANDAs did not contain specifications for or disclose the presence of NDMA and NDEA because of the failure by ZHP to identify and disclose the contamination—which would have precluded their sale. (HUAHAI-US00007752 (Ex. 16); PRINSTON00080011 (Ex. 17); ZHP01451842, -874 (Ex 27); PRINBURY00058078 (Ex. 28); PRINBURY00058083 (Ex. 29); PRINSTON00037968, -972 (Ex. 30); PRINSTON00183155 (Ex. 31); PRINSTON00177677 (Ex. 32); (TORRENT-MDL2875-00000003 (Ex. 61); TORRENT-MDL2875-00002771 (Ex. 63); TORRENT-MDL2875-00019489. (Ex. 64); TEVA-MDL2875-00680841 (Ex. 65); Barreto Dep. Vol. 597:3-14, 600:5-14 (Ex. 66)). In fact, the two DMFs affirmatively misrepresented that there was not NDMA or NDEA, stating, "there is not any high potency genotoxic group, such as, aflatoxin-like-, N-nitroso-, and azoxy-compound has been included in these impurities." (HUAHAI-US00007898-7899 (Ex. 16); PRINSTON00080118-80119 (Ex. 17)). It was ZHP's obligation to detect and disclose these unacceptable impurities, and ZHP cannot hide behind its own inadequate risk assessment. Per the FDA, "**You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing**

processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients." (ZHP01344159-62 (Ex. 6)).

The DMFs and ANDAs also stated the VCDs were USP compliant, and the USP never included a specification for NDMA or NDEA as approved impurities either. (ZHP01303141 (Ex. 33); ZHP02614594 (Ex. 34); PRINSTON00141349 (Ex. 35)). Importantly, the USP required that in the event of a manufacturing process change, analytical methods were required to be established to detect and identify impurities which encompassed nitrosamines, and also provided that any substance known to be toxic shall not be listed under the other impurities section thereby requiring specific identification. (Ex. 8, p. 4; Ex. 9, p. 9). USP defines toxic impurities as presenting "significant undesirable biological activity, even as minor components." (Ex. 10, p. 2). Genotoxic impurities, such as NDMA and NDEA, are toxic by definition, and can damage and mutate genes/DNA and then cause cancer. (ICH, *M7* p. 2, 10 (2013) ("This group of high potency mutagenic carcinogens ('cohort of concern') comprises aflatoxin-like-, N-nitroso-, and azoxy compounds.") (Ex. 1); FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) ("[T]here are some compounds containing certain structural groups (aflatoxin-like-, N-nitroso-, and azoxy-structures) that have extremely high carcinogenic potency and are excluded from the threshold

approach.") (Ex. 2); Ex. 15, p. 6; Ex. 20, p. 107, 152; Ex. 36, p. 17; Ex. 21, p. 12). NDMA and NDEA are a paradigmatic example of toxic impurities that drug manufacturers are required to identify, quantify, and then include in their specifications—and in this case, that would have precluded sale of the drugs containing those impurities. (Ex. 10, p. 2). The failure to do so is not a defense, it is a misrepresentation.

12. Defendants cannot argue that their VCDs were not adulterated because they complied with the USP monograph for valsartan.

As a corollary to the prior motion, the Court should prohibit Defendants from falsely arguing that their VCDs were not adulterated because they complied with the USP monograph for valsartan. As an initial matter, it is indisputable that the USP monograph for valsartan **does not** permit NDMA or NDEA. (ZHP01303141 (Ex. 33); ZHP02614594 (Ex. 34); PRINSTON00141349 (Ex. 35)). To the extent Defendants seek to argue that they complied with the *testing* requirements in the USP monograph for valsartan, this should also be precluded. The USP specifically required ZHP or any other manufacturer to develop whatever testing methods were needed to detect impurities from a new manufacturing process implemented by the manufacturer—as occurred here with ZHP. (Ex. 8, p. 4; Ex. 9, p. 9; Ex. 10, p. 2). The Court should thus prohibit Defendants from arguing that because the USP monograph did not explicitly require testing for nitrosamines, Defendants' API and VCDs (which contained nitrosamines) complied and were not adulterated. These

arguments would be entirely illogical, misleading, and unduly prejudicial, would require extensive countering, and should therefore be excluded under F.R.E. 403.

13. Defendants cannot argue "all drugs have impurities."

Defendants cannot be allowed to argue, suggest, or imply in any way that "all drugs have impurities" as if that is acceptable in general, because it conflates impurities in general with the impermissible, genotoxic impurities NDMA and NDEA that were present in Defendants' VCDs. This type of argument is irrelevant since the n-nitroso class of impurities is controlled very differently from non-genotoxic, non-probable human carcinogens, and what impurities may allegedly exist in other drugs is a distracting issue that is wholly unrelated to the claims in this action. FRE 401, 402. *See* ICH, *M7* p. 10 (2013) (Ex. 1); FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) (Ex. 2). Thus, in addition to the lack of relevance, this argument would confuse and mislead the jury by definition, in violation of Fed. R. Evid. 403.

14. Defendants cannot refer to the "alleged" presence of "purported impurities" or similar language, or dispute that all of the at-issue valsartan was contaminated, including untested lots (if any) at levels above the limits set by the FDA.

ZHP wants to try the case based on false facts. ZHP incredibly advised Plaintiffs that it wants to dispute that all of the API and finished dose at issue was contaminated with NDMA and/or NDEA. (Teva and Torrent equivocated). ZHP's corporate representatives confirmed that all of the at issue valsartan API and finished

dose was contaminated, at levels in excess of the levels eventually adopted by the FDA. The FDA was advised that "NDMA is present at a level greater than 0.5 ppm in all Huahai's drug substance batches for DMF 023491." (Hai Wang 3/10/21 Dep. Tr. 93:10-16, 154:3-16 (Ex. 26)); TEVA-MDL2875-00042637 (every batch of API from ZHP was contaminated) (Ex. 67); Barreto Dep. Vol. I at 201:10-202:9; 275:24-276:5; 367:19-368:2 (Ex. 57) (levels of NDMA in every batch of API expected to carry-over into finished dose). ZHP established that the NDMA levels in the API carried over to the levels in the finished dose because this was a process related impurity, "not a result of degradation of the product" and this information was provided by Prinston to the FDA. (*Id.* at 116:22-118:23, 144:15-147:1, 152:8-12, 158:8-159:6). **Dr. Li confirmed that every batch of valsartan manufactured with the zinc chloride process exceeded the FDA limit of 96 nanograms**. (Min Li 4/21/21 Dep. Tr., 306:15-23 (Ex. 5)). In fact, ZHP's testing for all USDMF grade valsartan, regardless of the process used, showed NDMA levels in excess of the FDA's limit for all but one batch, and that batch was sold to a non-defendant in this case. (ZHP02563814 (Ex. 37); ZHP02563015 (sending ZHP02563814 to the FDA with the title "Annex 1a.1_NDMA & NDEA test results for all ARBs in USDMF grade_20190413.xlsx") (Ex. 38); PRINSTON00158425 (stating that "An Excel spreadsheet of all ARBs USDMF grade (only US market) batches and their associated NDEA and NDMA finished batch testing results are provided in Annex

la.1.") (Ex. 39)).

Similarly, NDMA and NDEA are not "purported impurities," they are genotoxic impurities that, when discovered, resulted in a worldwide recall. Defendants should not be permitted to try to create doubt or questions for the jury on such fundamental points. F.R.E. 403. Extensive scientific and regulatory literature—admitted by ZHP's 30(b)(6) witnesses to be controlling—classifies these unapproved substances as genotoxic, probable human carcinogens. This is not a matter of interpretation. For example, the 2008 FDA Guidance relied on by ZHP describes the importance of identifying and controlling these harmful impurities. FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) (Ex. 2) This should not be permitted as it would be false, and by definition grossly misleading and confusing. F.R.E. 403.

Similarly, Defendants cannot assert that any untested lots or batches of the at issue API and/or VCDs (if any) was not or may not have been contaminated as with all of the lots and batches that were tested. This is pure speculation. There is simply no evidence to support such a denial, and the jury would be thoroughly misled if that assertion were to be made.

15. Defendants filed no cross-claims for contribution/indemnification, and disclosed no experts to do so, and should be precluded from asserting evidence or making arguments consistent therewith, including that a co-defendant was at fault, or liable for Plaintiffs' damages.

The Defendants did not assert cross-claims for contribution or indemnification against one another. Nor do they have experts asserting opinions against one another. Thus, they cannot assert or argue that their co-Defendants were at fault or are liable for the damages claimed. All they can do is attempt to defend their own conduct.

16. Defendants cannot assert the cost of replacement drugs or therapies.

Defendants should not be permitted to make any assertions as to the cost of any replacement drugs and/or therapies that would have been purchased if the contaminated VCDs were not available, or that were purchased by the TPP Trial Plaintiffs after the various recalls. Not only is such evidence completely speculative and unquantified, it is totally irrelevant to the issue at hand, which is: were the VCDs manufactured and sold by Defendants that which they purported to be at the point of sale, and if not, what is the amount of damages incurred by the TPPs due to purchasing the pills. This is akin to arguing that a thirsty person who purchased arsenic-laced milk has no damages because they would have purchased other milk anyway to satiate their thirst. The law does not permit tortfeasors to evade culpability in this ham-fisted manner.

Hypothetical, unquantified suggestions that the jury should offset the damages incurred by undefined amounts should not be permitted. Indeed, the Court has already determined that Defendants' VCDs were economically worthless *at the point*

of sale. (ECF 775 at 20 (emphasis added)). TPPs paid for adulterated and contaminated drugs that were economically worthless. Defendants should not be allowed to exploit the fact that patients had a continuing need for life-sustaining hypertension medication to reduce their liabilities.

17. Defendants cannot assert that the contaminated VCD's had value based on their efficacy.

Plaintiff's claims, and indeed this entire MDL, has never been about whether Defendants' VCDs worked to control blood pressure, though Defendants have attempted to set up that strawman argument to knock down throughout. The issue is the value of Defendants' VCDs that were adulterated, contained nitrosamines, were not cGMP-compliant, and did not meet compendial standards. Evidence about VCDs' efficacy is not relevant to any party's claim or defense under Fed. R. Evid. 401, and would be unduly prejudicial and confusing under Fed. R. Evid. 403. Moreover, even if the argument were otherwise admissible, Defendants' experts have been precluded from offering the opinion that the efficacy of the VCDs renders the contaminated pills valuable. (ECF 2581 at 12; ECF 2261 at 77-79).

18. Defendants cannot reference, assert, or rely on opinions of defense experts that rely on the precluded opinions of other defense experts. For example, Dr. Afnan's opinions that rely on Dr. Xue's precluded opinions.

Defendants took the position that this principle is so obvious that an MIL stipulation was unnecessary, but agreed. Then, when they received Plaintiffs' cross-motion to bar Dr. Afnan from giving opinions that rely on Dr. Xue's opinions, they

withdrew agreement. It is black letter law that the Court must exclude an expert's opinion if it is based on another already excluded opinion, whether it is from the same expert or a different one. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 789 (7th Cir. 2017) ("plaintiffs cannot reasonably admit through [a second expert] what they could not offer through [the excluded one]"); *Sims v. Kia Motors of Am., Inc.*, 839 F. 3d 393, 405 (5th Cir. 2016) ("[T]he district court properly excluded [the second expert's] theory ... because it relied on [the first expert's] inadmissible ... theory"); *Fuesting v. Zimmer, Inc.*, 362 F. App'x 560, 564 (7th Cir. 2010) ("[B]ecause [an expert's] testimony on causation primarily relies on an excluded expert opinion …, the district court did not err in excluding it."); *more generally In re Paoli Railrod Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (an "e*xpert must* have 'good grounds' for his or her belief"); *In re TMI Litig.*, 193 F.3d 613, 697 (3d Cir, 1999) (holding, "If the data underlying the expert's opinion are so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded."). Dr. Afnan's extensive reliance on the precluded opinions of Dr. Xue is an example of this rule in action. (ECF 2626-1, at 10-19). The Court should consequently bar any expert from referencing or relying on an excluded opinion in any manner.

19. Defendants cannot argue that the relevant warranties only went to the prescribers.

Defendants have indicated an intention to utterly confuse the jury and argue

that the representations considered by the TPPs are not the relevant representations. Instead, Defendants intend to argue that since patients rely on their physicians who prescribe the medication, the only representations that are relevant are those directed to the prescribers. The import of this is an effort to cut off reliance (to the extent needed).

This tactic would inject an issue that is completely irrelevant to the issues at trial, and would be confusing and misleading to the jury. First, this is not a learned intermediary doctrine case (as agreed by Defendants), so the prescriber is not the key recipient of information, unlike in a product liability failure to warn case. Second, the reality is that no doctor was prescribing a particular generic manufacturer's pills in the ordinary course. Rather, the doctors prescribed VCDs and left it to the pharmacy to dispense whichever generic form of valsartan they were stocking. Nor could or would the doctors have prescribed the contaminated VCDs if the contamination had been known. And all of this must be considered in light of the fact that the purchase transaction occurs at the retail counter when the patient and his/her TPP purchases the medication—and the TPP pays based on the representation that the medication is the approved, USP and Orange Book compliant formulation of valsartan. The prescriber is not a party to that transaction.

Defendants' FDA approval and USP warranties barred them from including NDMA and NDEA in their VCDs. Moreover, the FDA explicitly found Defendants'

VCDs contained adulterated API. (ZHP01344159 (Ex. 6)). The FDCA bars the sale of adulterated drugs. 21 U.S.C. § 331. A prescribing physician cannot override the terms of the FDA's approval, the USP's requirements, or the FDCA's bar on the sale of adulterated drugs. The Court should not allow Defendants to argue otherwise.

In addition, if the role of prescribers were to be an issue in the case, Plaintiffs would also have the right to call prescribing physicians as witnesses to demonstrate that no prescriber would or could have prescribed the valsartan contaminated with NDMA and NDEA. And if so, the TPPs would be third-party beneficiaries of the warranty provided to the prescriber and would prevail based on the doctor's testimony that he or she would not have prescribed VCDs if aware of the contamination issue. This would all be a waste of time and distraction.

20. Defendants cannot argue they are good companies, the "societal benefits" of their VCDs and other products, or the cost of drug research and development.

The Court should not permit Defendants to argue or suggest to the jury that the drugs they manufacture benefit society, nor should they be allowed to discuss the cost of drug research and development. Such arguments are the flip side to the MIL stipulation agreed to by Plaintiffs, agreeing not to disparage Defendants in general - which Defendants pulled down at the last moment when Plaintiffs asserted that stipulation should go both ways. Again looking at the opening statement by ZHP's trial counsel in the talc case is illustrative, including: "You don't stay in

business as long as J&J has by doing the types of things that were alleged here this morning." (Ex. 61, 543:20-24). Whether the Defendants are good or bad companies in general, or sell good or bad products in general is not the issue (aside from the punitive damages issues which will presumably be addressed in a second trial phase though that is not certain at present).

Defendants should be precluded from arguing or suggesting to the jury that they are "good companies" with "good reputations" that benefit society by making products that can improve people's lives, making charitable donations, or engaging in other acts that allegedly benefit the public. The only conceivable purpose for such evidence purporting that any Defendant is a "good company" is to create the impression with the jury that this "good company" is incapable—or at least unlikely—to make harmful products or irresponsible decisions. This is the sort of propensity evidence that is explicitly barred by Rule 404(a)(1), which prohibits the use of evidence of a person's character, character trait, or other acts to prove conduct in conformity therewith on a particular occasion. FR.E. 404(a)(1), (b)(1). This would also negate the stipulated MILs designed to preclude negative general evidence and open the door to a barrage of negative evidence directed at Defendants.

This is also clearly a sub-type of impermissible "good acts" evidence. Any such evidence, argument, reference, comment, or implication is unrelated to any fact at issue in this matter and constitutes inadmissible propensity evidence used to prove

conduct in conformity therewith. Evidence of such "good acts" is not permitted under Fed. R. Evid. 404(b). *U.S. v. Hayes*, 219 Fed. Appx. 114, 116 (3d Cir. 2007) (unpublished) ("The rule prohibits evidence of good acts if that evidence is used to establish the defendant's good character."); *Ansell v. Green Acres Contracting Co.*, 347 F.3d 515, 520 (3rd Cir. 2003).

21. Defendants cannot postulate a "but-for" world in which the contamination was disclosed earlier and the contaminated API and VCDs would have remained available for purchase.

At various times in this litigation, Defendants have tried to import antitrust pay-for-delay concepts about what the "but-for" world might have looked like if the nitrosamine contamination was fully disclosed earlier than the recalls in 2018. Defendants have done this to suggest, improperly, that TPPs or consumers might have chosen to continue buying adulterated VCDs even if they "knew the truth" about the contamination. This argument is legally impermissible because adulterated or NDMA/NDEA contaminated drugs cannot be sold in the first place. If "the truth" was known earlier, that would only mean the false warranties would have been withdrawn, the contaminated API and VCDs could not have been sold down the supply chain, and the recalls would have occurred sooner. It does not mean any VCD would have remained available on the market for TPPs or consumers to "choose" to buy. This argument is legally and factually unsupportable, would waste time, and mislead and confuse the jury, and therefore should be precluded under

F.R.E.. 401, 403. *See, e.g.*, *TecSec v. Adobe, Inc.*, 2018 WL 11388472, at *7 (E.D. Va. Nov. 21, 2018) ("proper for a Court at the motion in limine stage to preclude arguments at trial, such as the one at issue, without factual or legal support").

22. Defendants cannot reference double or treble damages, attorney fees, statutory penalties, pre- or post-judgment interest.

The laws of several states at issue for trial, as well as federal law and rules in some cases, permit double or treble damages, statutory penalties, pre- or post-judgment interest, attorney fees, and costs. *See, e.g.*, Fed. R. Civ. P. 23(h) (attorney fees and costs); 28 U.S.C. § 1961 (post judgment interest); N.J.S.A. § 56:8-10 (threefold damages); *Eagleview Techs., Inc. v. Xactware Solutions, Inc.*, 522 F. Supp. 3d 40, 69-70 (D.N.J. 2021) (prejudgment interest). Under Fed. R. Evid. 401 and 403, any reference to those remedies is irrelevant and would invite the jury to reduce improperly an award of actual damages. *See, e.g.*, *United States ex rel. Laymon v. Bombardier Transp. (Holdings) USA, Inc.*, 656 F. Supp. 2d 540, 547 (W.D. Pa. 2009) ("To instruct a jury on potential trebling of damages and statutory penalties would serve to inhibit the goals of awarding such damages..."); *see also Gulfstream III Assocs., Inc v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 448 (3d Cir. 1993) ("One purpose of the trebling provision is to encourage private plaintiffs to bring suit. Any ultimate recovery totaling less than three times proven damages would weaken the statutory incentive through judicial construction.").

23. Defendants cannot argue they complied with SOPs, guidances, or regulations without specifically identifying same; and specifically-referenced SOPs must have been produced in discovery.

Defendants likely intend to argue that they are not liable because they complied with their own SOPs, or with industry guidances or regulations. If Defendants argue this at trial, they must specifically identify *which* SOP, guidance, or regulation they claim they followed. Defendants should not be permitted to argue generally that that they "complied with all applicable SOPs, industry guidances, and regulations" without specifically identifying same, as this would inject undefined hearsay into the trial, and allow the jury to speculate as to what standards Defendants claim to have complied with.

Moreover, to the extent Defendants argue that they followed their own SOPs, those SOPs must have been produced in discovery. *See, e.g.*, *Monsanto Co. v. Bayer Bioscience N.V.*, No. 00-cv-1915, 2005 WL 5989796, at *19 (E.D. Mo. Oct. 28, 2005) (defendant cannot cherry-pick which documents to produce, and later which different unproduced documents on which to rely at trial); *Locke v. Jefferson Hills Manor*, 18-cv-1260, 2020 WL 5363320, at *4-5 (W.D. Sept. 8, 2020) (defendant cannot rely on undisclosed evidence).

24. Defendants cannot refer to their API or VCDs as "life saving" or similar descriptions.

The subject of this trial is the contamination of the valsartan and the economic consequences. That fact that the valsartan controlled blood pressure is not at issue.

Thus, Defendants should not be permitted to assert or argue that the valsartan was "life saving" or otherwise essential to society, or that the efficacy of the drugs outweighed the prohibited contamination rendering the pills adulterated or otherwise unacceptable. Such arguments would be irrelevant, and clearly misleading and unduly prejudicial. F.R.E. 401, 403.

25. Defendants cannot assert or argue that the prescription of VCDs was standard of care.

The standard of care never required the use of valsartan to treat hypertension. Rather, it was acceptable to prescribe valsartan, but also acceptable to prescribe numerous alternative medications and treatment regimens—almost all of which were not contaminated with genotoxic carcinogens. It would be confusing and misleading to inject the concept of standard of care into the trial, and that concept should not be introduced.

26. ZHP Defendants cannot assert any evidence or argument inconsistent with their filed stipulations.

During discovery Plaintiffs filed a motion for sanctions based on obstructive conduct by ZHP's then counsel and ZHP's witnesses. The Court ordered continued deposition testimony to address multiple areas of questioning. ZHP proposed a stipulation to address a number of the areas in question and a stipulation was agreed to. (Ex. 48). In sum, the stipulation demonstrates the complete lack of scientific analysis of the potential consequences of the introduction of the DMF and TEA, and

their known impurities, along with the use of sodium nitrite, to the new processes. ZHP must now abide by the terms of the stipulation and not assert or argue that the terms of the stipulation are not controlling, or submit evidence and arguments contradicted by the stipulation.

27. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA did not issue Warning Letters to them.

Teva's and Torrent's liability experts attempted to opine that their respective VCDs were not adulterated, and cannot be considered adulterated, because the FDA never issued a warning letter or other formal pronouncement to that effect. In acknowledging that the Warning Letter directed to ZHP is dispositive, they fail to grapple with the fact that it is also dispositive as to them. This is because the use of adulterated API to manufacture finished dose renders the finished dose adulterated as well. That is why all of the contaminated finished dose had to be recalled.

Related, this Court rightly precluded the defense experts' position that adulteration cannot be defined retrospectively, designed to avoid the Court's application of the controlling definition of adulteration which clearly encompasses the VCDs, because it "is sophistry, which attempts to avoid a retrospective characterization of Teva's finished dose products as 'adulterated' from the state of the nitrosamine contamination." (ECF 2581 at 17). Just as this Court already precluded Defendants' experts from testifying about their illogical sophistry, so, too, should the Court preclude Defendants' counsel from making the same arguments to

the jury, which would be non-probative (*see* Fed. R. Evid. 401) and unduly prejudicial, misleading, and confusing (*see* Fed. R. Evid. 403).

28. Defendants cannot argue that they complied with cGMPs' in the manufacture of the API and VCDs.

This MIL parallels a dispositive motion filed by Plaintiffs. The FDA found that ZHP violated cGMPs in its November 29, 2018 Warning Letter to ZHP, and that this led to the contamination of the valsartan.

> **Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated** within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).
>
> * * *
>
> **Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine. . .**
>
> **You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients**.

(ZHP01344159-62 (Ex. 6)). ZHP's witnesses confirmed the lack of diligence in the development and risk assessment of the processes multiple times, including:

- Peng Dong confirmed that the **ZHP internal protocol titled: Guideline for Genotoxic Impurity Evaluation** (No. API-R&D-002) (bates ZHP01447235-242 (Ex. 11)), Section 2, provided that, "**All intermediates and APIs produced under GMP conditions must be identified for genotoxic impurities," and per ICH the risk assessment evaluation included identification of genotoxic impurities and confirmation of the quality specifications of any API, including valsartan**. (Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (Ex. 12)). Obviously, ZHP failed to do this for NDMA and NDEA in its valsartan.

- Eric Gu confirmed that ZHP was required to evaluate both the "main reactions" and "side reactions," such as those creating NDMA and NDEA, but he explained ZHP's faulty "focus" as follows: "Yes, when you say you should, a lot of things you should, yeah. But as I said, you know, we focus on the main reactions." (Eric Gu 4/6/2021 Dep. Tr. 84:14-84:23 (Ex. 4)).

- Mr. Gu also agreed that the "scale-up process from lab to pilot and then to commercial," was "required by good manufacturing practices," and that "ZHP did not do the pilot scales" for the ZnCl2 process. (*Id.* at 420:3-7, 420:9-10, 421:11-12).

- When asked why, despite every batch showing the "NDMA peak just after the Toluene peak on the chromatograms. . . nobody at ZHP realized that it needed to be tested and identified," Mr. Gu stated that ZHP was aware of these peaks and, "did whatever they can," but ultimately that, "**They are struggling, I guess, in the past**." (*Id.* at 333:21-335:19).

29. Defendants cannot argue that the contaminated API and VCDs were not adulterated.

The FDA found in its November 29, 2018 Warning Letter, that ZHP's API was adulterated. (ZHP01344159 ("Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API

are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).") (Ex. 6). The VCDs incorporating that contaminated API are also adulterated by definition, and this was communicated to Torrent by the FDA. (TORRENT-MDL2875-00072716 ("FDA communicated that they consider these batches adulterated. Please confirm this batch of API was only used in these 5 lots of finished goods.") (Ex. 13)). The FDA placed ZHP on an Import Ban of all drugs from ZHP's manufacturing facility as a result of the finding in the Warning Letter. (ZHP00061080 (Ex. 14)). As demonstrated in Plaintiffs' motion for partial summary judgment, the massive cGMP violations, and the failure of the adulterated API and VCD's to satisfy the compendial requirements for quality, clearly satisfy the statutory definition of adulteration:

> **(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture…**
>
> … (2)…(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; ….
>
> **(b) Strength, quality, or purity differing from official compendium**

> If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. ….

21 U.S.C. §. 351(a)(2)(B), (b). Therefore, Defendants should be precluded from denying the adulteration.

30. Defendants cannot argue that the contamination was unavoidable or unforeseeable.

Defendants have repeatedly refused to take responsibility for their manufacture and sale of contaminated valsartan, arguing that nobody could have known this would happen. First, that assertion is categorically untrue, as found by the FDA in the Warning Letter to ZHP. (ZHP01344159-62 (Ex. 6)). In addition, Dr. Xue, the only expert ZHP had to address this issue, has had those opinions barred. (ECF 2581 at 17-18). Thus, although ZHP did not foresee the chemical reactions causing the contamination, that was due to its carelessness; it cannot say that it was unforeseeable. In fact, the draft of ZHP's Deviation Investigation Report admitted that the risk assessment failed due to "insufficient" analysis and understanding. (ZHP00662308 (Ex. 54)). Second, there was nothing that required ZHP to change its valsartan API manufacturing process from the TIN process used to manufacture the RLDs with no contamination issues, to the TEA with sodium nitrite and zinc chloride processes—all in the pursuit of lower cost, higher yield, and increased market share. (PRINSTON00162373 (Ex. 40)). That was a deliberate, conscious,

profit driven decision, and the consequences are the responsibility of Defendants.

31. Defendants cannot argue that Teva's and Torrent's VCDs were not adulterated because the FDA never declared their VCDs did not meet USP standards or never de-listed the VCDs from the Orange Book.

Teva and Torrent also should be precluded from arguing that their VCDs were not adulterated because the FDA never formally pronounced that their VCDs did not meet USP standards or never de-listed the VCDs from the Orange Book. We know that the drugs did not meet USP standards that did not permit NDMA or NDEA, and that the unacceptable purity and quality deficits destroyed the therapeutic equivalence of the contaminated drugs. This is not up for debate—it required a recall—and trial time would be wasted debating these points. This also "is sophistry, which attempts to avoid a retrospective characterization of Teva's finished dose products as 'adulterated' from the state of the nitrosamine contamination." (ECF 2581 at 17). Such improper argument should be precluded for the same reasons outlined above.

32. Teva and Torrent cannot argue that they were not responsible for the quality of the API incorporated into their finished dose VCDs.

As a matter of law, an ANDA holder (i.e., a finished dose generic drug manufacturer) is responsible for the quality of all aspects of its own drug, including the API incorporated therein. *See, e.g.*, *United States v. Vepuri*, 21-cr-132, 2022 WL 541772, at *8 (W.D. Pa. Feb. 23, 2022) (sustaining criminal indictment charging ANDA holder for selling finished dose generic with improper API sourced from

third party).

As set forth with regard to MIL 2 above, Defendants have admitted that they were responsible for the quality of the drugs they manufactured and sold. Defendants cannot disclaim this admission at trial.

33. Defendants cannot raise the notice issues raised on the dispositive motions at trial.

Defendants have indicated that they want to raise the pre-suit notice issue that is pending before the Court, at trial. This is a legal point, not a point as to the operative facts in the case. If decided in Plaintiffs' favor there is no issue to raise. If the Court determines that there is a fact question, the Court and the Parties should discuss how that issue will be presented at that time.

34. Defendants cannot assert irrelevant, confusing, misleading, or unduly prejudicial background facts about MSP or its assignors.

Defendants should not be allowed to introduce or assert irrelevant, confusing, misleading, or unduly prejudicial background information about MSP, companies affiliated with MSP, or MSP's assignors. This is the flip side to stipulations Plaintiffs agreed to in order to prevent similar attacks on Defendants, for example agreeing not to discuss Teva's role in the opioid litigation. But Defendants want an unfair one way street.

Defendants have made clear that they intend to turn this case into a sideshow about MSP, and litigate unduly prejudicial matters that are absolutely irrelevant to

this case. For example, in the deposition on MSP's damages expert, Rena Conti, Defendants asked Dr. Conti the following question:

> Q. Did you authorize MSP to use Judge Kugler's ruling on the admissibility of your expert opinion in connection with defending themselves in a lawsuit that alleges they committed fraud and are running a ponzi scheme?

(R. Conti Dep. Tr. 50:16-21 (Ex. 68)). Six days later, Defendants doubled down and asked Emblem's corporate representative substantially the same questions in his deposition:

> Q. Are you aware that MSP has been sued by another health insurer, Cano Health, for fraud?
> MR. KASS: Objection to form and outside of the scope.
> THE WITNESS: I am not aware, no.
> BY MS. BRANCATO: Q. Are you aware of any lawsuits filed against MSP by any other insurance companies?
> MR. KASS: Same objections.
> THE WITNESS: No, I'm not aware.
> BY MS. BRANCATO: Q. Are you aware that in the complaint by Cano Health against MSP, they called MSP a sham and a Ponzi scheme?
> MR. KASS: Same objections.
> THE WITNESS: I am not aware. Do you have any reason to disagree with that statement by Cano Health?
> MR. KASS: Objection to form.
> THE WITNESS: I'm not sure what you're asking. Can you repeat the question?
> BY MS. BRANCATO: Q. Do you have any reason to disagree with the statement by Cano Health that MSP is a Ponzi scheme or a sham?
> MR. KASS: Same objections.
> THE WITNESS: I don't know what their basis is for saying that, so I can't comment.

(A. Colby Dep. Tr. 29:12-30:19 (Ex. 69)). They also asked Mr. Colby about civil and criminal investigations into an affiliated MSP entity:

> Q. Mr. Colby, are you aware that MSP has been the subject of criminal and civil investigations?
> MR. KASS: Object to scope. Outside the noticed deposition topics.
> MS. BRANCATO: You can answer.
> THE WITNESS: I do not.
> BY MS. BRANCATO: Q. You're not aware that MSP has been subject to civil and criminal investigations. Correct?
> A. That's correct. I am not aware.
> MR. KASS: Same objection.

(*Id.* at 28:21-29:9).

And in the deposition of MSP's corporate representative, Jorge Lopez, Defendants asked him about the number of cases filed by MSP and its affiliates:

> Q. How many cases has MSP or any of its affiliates filed as a plaintiff?
> A. Specific number, I could not tell you.
> Q. Is it more than 100?
> A. I would say yes.
> Q. Do you know how many class actions MSP or one of its affiliates have filed as a punitive class representative?
> A. I don't recall a specific number.
> Q. How many of MSP's lawsuits have been dismissed involuntarily?

(J. Lopez Dep. Tr. 162:22-163:9 (Ex. 70)). Defendants also asked about assignments that have nothing to do with the claims that MSP brings in this lawsuit:

> Q. I'll broaden the question. How many assignments has the plaintiff MSP or MSP Recovery or any series of MSP received since the formation of those entities?
> A. I don't have an exact count, but many.
> Q. Okay. Understanding you don't have an exact count at your fingertips, do you have an approximate count?
> A. I would say approximately greater than 100 and approximately less than 150, but that would just be a guess.

(*Id.* at 66:9-21).

As will be shown further below, those lines of questioning have nothing to do with this litigation and will only serve to provide ammunition for one of Defendants' central litigation tactics—a full-on assault on Plaintiff in an effort to dirty Plaintiff and divert the jury from the issues. This would unduly prejudice MSP. Plaintiffs provide further examples of unduly prejudicial arguments and evidence that Defendants may attempt to introduce at trial, and which the Court should exclude in total.

a. The Litigation Between Life Wallet and Cano Health ("Cano")

As shown above, Defendants have not been shy about trying to inject the Cano litigation into this case. But that litigation has nothing to do with whether Defendants sold contaminated VCDs, and it also has nothing to do with the plaintiff in this action: MSP. The Cano litigation was brought against MSP Recovery, Inc. d/b/a LifeWallet ("LifeWallet"), which is a thrice-removed corporate parent of the plaintiff, and it relates to claims that Cano assigned to LifeWallet. That lawsuit is focused on by the defense because it contains Cano's unsupported allegations of a "Ponzi scheme" and fraud against LifeWallet (an allegation LifeWallet has strongly disputed in its Verified Motion to Strike Cano's complaint as a sham). Any testimony, documents, or argument relating to the Cano lawsuit is not only non-probative to the issues before the jury, but would only serve to confuse or mislead the jury and unduly prejudice MSP. F.R.E. 401 and 403.

b. Reported Investigations by the S.E.C. and United States Attorney's Office for the Southern District of Florida into Life Wallet

The Court should also exclude any attempt by Defendants to introduce evidence or elicit testimony related to a reported investigation by the S.E.C. and the U.S. Attorney's Office into LifeWallet related to LifeWallet's merger with a special acquisition company. First, those investigations have nothing to do with whether the Defendants manufactured and sold contaminated VCDs—which is the issue in this case. Second, those investigations have reportedly been directed towards LifeWallet and MSP Recovery, LLC ("MSP Recovery"), *neither of which are plaintiffs in this action*. Those investigations are simply irrelevant.

Further, even if the investigations were directed to Plaintiff (they are not) such investigations should still be excluded under Rule 403 because of the risk of undue prejudice. Courts routinely exclude bad acts *committed by a party*. *See Bhaya v. Westinghouse Elec. Corp.*, 922 F.2d 184, 188–89 (3d Cir. 1990) ("Evidence that a party committed wrongs other than those at issue in a case often creates a danger of 'unfair prejudice' because such evidence may influence a jury to return a verdict based on a desire to punish for the other wrongs."). *A fortiori*, the Court should exclude a mere *investigation* into potential bad acts. *In re Bankatlantic Bancorp, Inc. Sec. Litig.*, 2010 WL 11426137, at *3 (S.D. Fla. Aug. 20, 2010) ("[T]he Court concurs that evidence of the [ongoing and incomplete] SEC investigation should be excluded pursuant to Federal Rules of Evidence 401, 402 and 403.").

c. MSP's Business Model

As shown above, Defendants intend to criticize MSP's business model and introduce argument and evidence that paints MSP as opportunistic, litigious, and unworthy of a recovery. To date, they have already questioned witnesses about the number of assignments that MSP has acquired, the number of lawsuits that it has filed, and the number of lawsuits that have been involuntarily dismissed. Defendants would no doubt continue this at trial—absent an order by the Court. None of that is relevant to the central issue in this case: Defendants' manufacture and sale of contaminated VCDs—and such arguments are unduly prejudicial. The Court should exclude that evidence and argument under Rules 401 and 403.

For the same reasons, the Court should exclude reference to any negative statements made by courts about MSP and its affiliated entities. For example, the Defendants should not be able to introduce the following statement from a completely unrelated litigation: "[P]laintiffs pull the litigation trigger before doing their homework. They sue to collect on receivables they paid little or nothing for and then rely on the discovery process to show they acquired something of value and thus have an enforceable right to collect." *MAOMSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.*, 994 F.3d 869 (7th Cir. 2021). There is no world in which it would be proper or fruitful for the Parties to burden the jury here with competing narratives about that or any other unrelated case. Nor should they be able introduce

this statement: The Southern District of Florida is "well aware of the numerous MSP Act cases with which Plaintiffs have clogged this District." *MSP Recovery Claims, Series LLC v. Bos. Sci. Corp.*, 2019 WL 180125, at *2 (S.D. Fla. 2019). Those statements are unduly prejudicial to be introduced to a jury factfinder and would undoubtedly confuse the issues.

The Court should also not permit Defendants to reference evidentiary findings by other courts about MSP's data. For example, they should not be able to introduce evidence showing that data produced in another litigation was found at the summary judgment stage to be created for litigation and not a business record. *E.g.*, *MAO-MSO Recovery II, LLC v. Farmers Ins. Exch.*, 2022 WL 1690151, at *12 (C.D. Cal. 2022). In addition to confusing the jury and being unduly prejudicial, such information would be impermissible propensity evidence. The evidence that matters here is the evidence used in this trial.

d. LifeWallet's Financial Condition

The Court should also prevent Defendants from introducing any evidence or testimony related to LifeWallet's financial condition, including, but not limited to, its restated financial statements, operating losses, and stock price. LifeWallet is the thrice-removed parent company of MSP; it is not the plaintiff in this action. Even if it were the plaintiff, any evidence or testimony about LifeWallet's finances would be irrelevant and would only serve to confuse and mislead the jury and prejudice

MSP. Fed. R. Evid. 401, 403.

e. Issues Related to MSP's Assignors

The Court should also exclude any attempt by Defendants to introduce or elicit irrelevant, confusing, and unduly prejudicial arguments and testimony related to MSP's assignors. For example, in the deposition of SummaCare's corporate representative, Defendants asked about SummaCare's temporary removal from the Medicare Part C and Part D program after CMS found that SummaCare "failed to comply with CMS requirements regarding Part C and Part D appeals and grievances and organization/coverage determinations." (*See* Enforcement Letter from CMS at 2 (Ex. 45); T. Mrakovich Dep. Tr. 47:15-48:17 (Ex. 44)). Any testimony, documents, or argument related to the above will only serve to confuse or mislead the jury, and require a mini-trial as to what happened. CMS's decision to temporarily sanction SummaCare is unrelated to the core issues in this case, SummaCare's purchase of tainted VCDs manufactured and sold by the Defendants. Fed. R. Evid. 401 and 403.

***f.* Defendants Cannot Argue that MSP Is Merely an Assignee of SummaCare and Emblem and That It Is Not a Health Plan That Paid for Valsartan**

The Court should also exclude any argument or evidence that would highlight MSP's status as an assignee of SummaCare and Emblem and not a health plan that paid for VCDs. It is well established that "[a]n assignee 'stands in the shoes' of an assignor and thus acquires the assignor's right 'to bring suit for collection of monies

owed to the assignor."' *ImagePoint, Inc. v. JPMorgan Chase Bank, Nat. Ass'n*, 27 F. Supp. 3d 494, 502 (S.D.N.Y. 2014) (quoting *Sompo Japan Ins. Co. of Am. v. Norfolk S. Ry. Co.*, 966 F. Supp. 2d 270, 279–80 (S.D.N.Y. 2013)); *Cameron v. Hess Corp.*, 974 F. Supp. 2d 1042, 1055 (S.D. Ohio 2013) (same).

Defendants will try to convince the jury that MSP is not worthy of a recovery because: (1) it is not a health plan that paid for the defective VCDs, it merely is an assignee that purchased claims after the fact, and (2) any recovery in the case would go to MSP and not the health plans that were harmed when they paid for the defective VCDs.

Those arguments have no probative value; whether MSP paid for the defective VCDs and whether any recovery would go to MSP and not the health plans is legally irrelevant. Emblem and SummaCare *did pay* for the defective and contaminated VCDs, and thus they *were harmed* when they paid for the defective and contaminated VCDs, and as their assignee, MSP has the legal right to recover for that harm. As such, those arguments and any related evidence would be irrelevant, and even if they had tangential relevance, such evidence would be misleading and unduly prejudicial. F.R.E. 401, 403. The only reason for such argument and evidence would be to influence the jury to believe that MSP is not worthy of any recovery with the hope that the jury makes a "decision on an improper basis." *Bhaya v. Westinghouse Elec. Corp.*, 922 F.2d 184, 188–89 (3d Cir. 1990) (citing Advisory

Committee Note on Rule 403).

Plaintiffs cannot envision all ways in which Defendants may try to smear MSP, or hammer MSP's position as an assignee to improperly influence or mislead the jury, and for that reason, it does not limit this motion in limine to those specific arguments or evidence listed. Instead, MSP asks the Court to issue a blanket order precluding the delineated arguments and related evidence and any other arguments or evidence that would similarly attack MSP, or highlight MSP's status as an assignee.

35. Defendants cannot argue or suggest that TPP Trial Subclass Plaintiffs/Members will retain any benefit and not pass it along to their insureds.

The Parties have already agreed that Defendants will not argue Plaintiff and subclass members will pass-on costs to insureds if they lose at trial (e.g., higher premiums), and conversely Plaintiff will not argue that they will pass-on savings to insureds if they win at trial (e.g., lower premiums). This *in limine* request is a corollary of the Parties' agreement. Just as the Parties will not argue what effect a verdict will have on insureds' premiums, so too, should Defendants not argue or suggest that Plaintiff and subclass members might line their own pockets without regard to insureds. Again, this is an attack on Plaintiff designed only to unfairly prejudice the jury. The impact a verdict here will have on insureds, positive or negative, simply is irrelevant and unduly prejudicial under Fed. R. Evid. 401and 403.

Otherwise, Defendants could evade their agreement simply by suggesting a verdict for Plaintiff and subclass members will not go where intended. The jury should not give any consideration to what impact a verdict might or might not have on insureds.

36. Defendants cannot argue Medicare Part D Offsets (collateral source; reconciliation process).

Defendants should not be permitted to argue to the jury that monies paid by the Centers for Medicare and Medicaid ("CMS") under Medicare Part D should be offset against any damages award to Plaintiff and the subclasses. Medicare monies are not guaranteed, and are paid well after the fact of a transaction. More fundamentally, they are a collateral source of payment and, therefore, are precluded under the collateral source rule. The rule provides that "a tortfeasor should be held accountable for the wrong done and should not benefit from the fact that the victim later escapes some of the consequences of the harm." *In re HIV Antitrust Litig.*, No. 19-cv-2573, 2023 WL 3603732, at *2 (N.D. Cal. May 23, 2023) (granting motion *in limine* precluding defendants, including Teva, from arguing to jury that Medicare monies are offsets). The collateral source rule arises from "common law, and most, if not all, states have adopted the approach that a statute does not abrogate common law unless it is clear that the legislature so intended." *Id.*

This Court should follow two very recent decisions, *In re HIV* and *In re Zetia*. *In re HIV* was an MDL class trial (like this case), and also involved Teva. Judge Chen precluded the defendants from arguing to the jury that Medicare monies are

offsets, citing the collateral source rule. *Id.* He further held that, to the extent there might be an offset argument, that was for the court, not the jury, to decide:

> But Plaintiffs have pointed out – and Defendants do not dispute – that it is a decision *for the Court*, and not the jury, as to what should happen in these minority states. Accordingly, for purposes of the *jury trial*, Defendants shall not be permitted to raise Medicare payments as a set-off to Plaintiffs' damages. Should Plaintiffs prevail at trial, then there may need to be a limited bench trial on the issue of Medicare payments and set-off.

Id. Similarly, in another MDL, *In re Zetia (Ezetimibe) Antitrust Litigation*, No. 18-md-2836, 2023 WL 3064462 (E.D. Va. Apr. 18, 2023), the court precluded evidence and argument to the jury (including opinions of Dr. Laura Stiroh, one of Defendants' experts here) about Medicare monies under the collateral source rule and that it would only mislead and confuse the jury:

> The same reasoning holds with regard to government payments through Medicare Part D. The only difference is that the individual consumer pays the premiums for regular health insurance plans, while the government subsidizes the premiums for Medicare Part D plans. But like typical insurance premiums, government payments under Medicare Part D are set in advance and are not calculated based on purchases of specific drugs

Id. at *5. The *In re HIV* and *In re Zetia* decisions comport with other courts' rulings in similar situations. *See, e.g.*, *Egan v. United States*, No. 15-cv-3533, 2018 WL 1940390 (D.S.C. Apr. 25, 2018) (collateral source rule precluded argument that VA benefits offset plaintiff's damages); *EEOC v. Aldi, Inc.*, No. 06-1210, 2008 WL 5429624 (W.D. Pa. Dec. 31, 2008) (collateral source rule barred unemployment

benefits offsetting backpay award); *Falconer v. Penn Maritime, Inc.*, 397 F. Supp. 2d 62 (D. Me. 2005) (precluding evidence of plaintiff's prior receipt of social security disability and Medicare benefits per collateral source rule); *Amlotte v. United States*, 292 F. Supp. 2d 922 (E.D. Mich. 2003) (Medicare Part A and B payments could not be offset against plaintiff's damages, as these monies came from a collateral, not direct, source).

37. Defendants' cannot suggest that there should be set offs for unquantified, speculative subsidies and reimbursements.

Similarly, Defendants cannot suggest that Plaintiff's damages should be reduced by unquantified, speculative subsidies and reimbursements. Defendants have put forth no alternative damages calculation and therefore any testimony based on what manufacturers sold VCDs for is completely unsupported in the record for trial. In any case, such a calculation (even if one was presented through Defendants' experts, it is not) lacks a reliable methodology. The measure of damages is what Plaintiff and TPP class members paid at the point of sale (not any upstream transaction) In addition, Defendants have not been able to demonstrate even the existence of any reimbursements or other offsets paid to downstream customers. Nor could they. As set forth in Plaintiffs' motion to exclude Wayne Gibson, even the retail pharmacy defendants in this case admit that there is no such thing as valsartan direct and indirect remuneration ("DIR"), and Mr. Gibson's position that any DIR should be accounted for is purely speculative.

38. Defendants cannot reference the dollar amounts for which they sold the API and VCDs, and the amounts of the reimbursements requested and/or agreed to with regard to downstream customers.

The amounts for which the API and VCDs were sold by Defendants into the supply chain are irrelevant. The damages at issue are the amounts paid by Plaintiffs. In addition, the extent to which any reimbursements were offered, made available, or paid by Defendants to any downstream customer are also irrelevant. These amounts should not be referenced as they will confuse and mislead the jury as to the proper calculation of damages in this trial. F.R.E. 401, 403.

39. Defendants cannot disparage the insurance industry.

Defendants and/or their counsel cannot make disparaging statements regarding the insurance industry and its practices in an effort to suggest that Plaintiffs' practices or conduct in this case is consistent with negative perceptions of the industry. That would have no probative value and would be beyond the scope of this case. Any such effort would only serve to prejudice the jury against Plaintiffs. *See Old Chief v. U.S.*, 519 U.S. 172, 181 (1997) (stating that, generally, "propensity evidence" regarding prior occurrences is inadmissible). Therefore, Defendants should not be permitted to present evidence, testimony, or argument that is aimed solely at prejudicing the jury against Plaintiffs because of Plaintiffs' status as insurance companies, or because of alleged experiences with other insurance companies.

40. The Court should not permit Defendants to discuss how a verdict would economically affect either Defendants or society. This sort of conjecture is non-probative, prejudicial, and should be excluded.

Defendants should not be permitted to discuss how a verdict would economically affect Defendants. (This motion does not address arguments that may be made in connection with a punitive damages phase). Courts have held that appealing to the sympathy of jurors through references to the relative wealth of the Parties may be cause for reversal. *See, e.g.*, *Draper v. Airco, Inc.*, 580 F.2d 91 (3d Cir.1978); *Adams Labs., Inc. v. Jacobs Eng'g Co., Inc.*, 761 F.2d 1218, 1226 (7th Cir. 1985) *Edwards v. Sears, Roebuck & Co.*, 512 F.2d 276 (5th Cir.1975). There is no probative value in allowing such evidence when the Parties' financial status is not at issue, though there is great risk of prejudice. Fed. R. Evid. 403; *e.g., Gordon v. Wal-Mart Supercenter*, 2009 WL 3850288 (S.D. Ala. Nov. 12, 2009). *See, e.g., Waite v. Neal,* 918 F.Supp. 133, 134 (E.D. Pa.1996), ("remarks which are not supported by the evidence and which are designed to appeal to the jury's prejudice or passion such as the golden rule argument are also improper...").

41. Defendants cannot argue TPP Trial Subclass Plaintiffs/Members are "sophisticated users" (see affirmative defense).

Defendants raised for the first time in their recently-filed Answers that they may affirmatively assert that Plaintiff and TPP trial subclass members are "sophisticated users." Defendants have made absolutely no showing, and there is no evidence, that Plaintiff MSP, its at-issue assignors Emblem or Summacare, or any

absent class member is a "sophisticated user" of VCDs. Indeed, it is not even clear what a "sophisticated user" means in the context of this economic loss class trial; this is not a strict liability or product misuse case. *See, e.g.*, *Scantlin v. GE Co.*, No. 10-0333, 2014 WL 12579811, at *1 (C.D. Cal. Feb. 21, 2014) (sophisticated user defense unavailable under California law outside strict liability failure-to-warn claim). Absent demonstration the defense is legally applicable, let alone a sufficient factual showing to satisfy invocation of the defense, "sophisticated user" argument by Defendants is not probative of any claim or defense (*see* Fed. R. Evid. 401), and would be unduly prejudicial, misleading, and confusing (*See* Fed. R. Evid. 403).

42. Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms "we," "us," and/or "our" when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial.

Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms "we," "us," and/or "our" when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial. *See, e.g.*, *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2021 WL 918214, at *6 (N.D. Fla. Mar. 10, 2021) ("counsel should avoid making a personal connection with their clients in front of the jury."). This again can be exemplified by the opening statement of ZHP's trial counsel in the talc trial: "he accused **us** of selling a product for babies that cause cancer," "**We** employ over 40,000 people in the United States…some of the folks that **we employ right here in Miami**…" "**we** had a whole program looking

for alternative mine sources," "**we** hired the best lab in the country." (Ex. 61, 537:3-7, 543:25-544:3, 565:11-14, 566:16-17). Such language leads the jury to believe that counsel for Defendants have personal knowledge of the facts, is calculated to generate sympathy from the jury through implication that the attorneys are parties to the litigation, and encourages the jury to base its decisions on factors other than the law.

43. Defendants cannot criticize plaintiff attorneys, plaintiffs for bringing lawsuits, or reference attorney advertising.

Defendants inexplicably would not agree that they will not resort to an attack on plaintiffs and plaintiff attorneys. This should be prohibited. The Parties agreed there will be no mention of tort reform, a litigation crisis, or otherwise make critical comments of lawsuits in general. However, Defendants assert this does not preclude them from arguing this is a lawyer-driven litigation, criticizing Plaintiff's counsel and "the way MSP does business," and pointing to attorney advertising. Each of these arguments should be excluded.

This Court should exclude any evidence or testimony insinuating that this case is a result of "lawyer-driven litigation." Not only is such evidence or testimony irrelevant to the triable issues in this case, but it is highly prejudicial and will confuse the jury. This language is very similar to, and will evoke similar prejudices as the phrases "litigation crisis," and "lawsuit abuse," which Defendants have already agreed not to mention, given their irrelevant, prejudicial nature. Therefore, any

mention of "lawyer-driven" litigation should be excluded as well. See, e.g., *In re Bard IVC Filters*, 2018 WL 934795, at *2 (D. Ariz. Feb. 15, 2018) (excluding mention of "tort reform or any perceived 'litigation crisis'" as irrelevant); *In re Xarelto*, 2017 WL 11718344, at *2 (E.D. La. Apr. 18, 2017) (excluding comments regarding "Alleged 'Litigation Crisis,' 'Lawsuit Crisis,' 'Lawsuit Abuse,' or 'Lawyer-Driven Litigation.'"); *In re Vioxx*, 2005 WL 3164251, at *1 (E.D. La. Nov. 18, 2005) (precluding "[a]ny reference to 'litigation crisis,' 'lawsuit crisis,' 'lawsuit abuse,' or any other similar term or phrase"); *In re Actos*, 2013 WL 5603823, at *2 (W.D. La. Oct. 10, 2013) (excluding reference to "litigation crisis, lawsuit crisis, lawsuit abuse, or similar concepts or phrases."); *Dedrick v. Merck & Co., Inc.(In re Vioxx)*, 2006 WL 8472994, at *1 (E.D. La. Nov. 22, 2006) (precluding "[a]ny mention of the purported 'litigation crisis,' 'lawsuit crisis,' 'lawsuit abuse,' or similar terms or phrases").

Further, Plaintiff anticipates Defendants will assert that MSP is "litigious" or allegedly brings lawsuits as a business practice, as discussed above. Any such argument or commentary should be excluded as it is highly inflammatory and will confuse and mislead the jury. *Ostroff v. Security Sav. Bank*, 1992 U.S. Dist. LEXIS 12322 (E.D. Pa. Aug. 18, 1992) ("The charge of litigiousness is a serious one, likely to result in undue prejudice against the party charged…"). Federal Rule of Civil Procedure 404(b) is quite clear that introduction of previous lawsuits to argue a

propensity for filing lawsuits is improper. See *Otto v. Commerce St. Capital,* CIV.A. 12-2472, 2013 WL 2357623, at *2 (E.D. Pa. May 29, 2013) ("[d]efendants may not introduce evidence of [Plaintiff's] other lawsuits for an improper purpose under Rule 404(b), that is, to show that [Plaintiff] has a propensity for filing lawsuits"). Related, any mention of Plaintiff's prior lawsuits should also be excluded under Federal Rule of Civil Procedure 401 and 403, as this is information is irrelevant, highly prejudicial and will confuse and mislead the jury. See *Blancha v. Raymark Indus*., 972 F.2d 507, 516 (3d Cir. 1992) (listing evidence relating to previous litigation involving the parties as evidence that is "routinely excluded" under Rule 403); *Covell v. Bell Sports*, *Inc.,* CV 09-2470, 2010 WL 11561087, at *2 (E.D. Pa. July 13, 2010) (excluding reference to Plaintiff's previous lawsuit involving the same facts as "any probative value of Plaintiffs' previous lawsuit is certainly outweighed by its prejudicial effects."). Just as Plaintiffs will not introduce evidence of prior unrelated lawsuits against Defendants, Defendants should be precluded from referencing unrelated lawsuits brought by or against Plaintiff.

44. The manner in which Plaintiff learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them, is irrelevant and unrelated to Plaintiff's claims and subject to attorney-client privilege.

The manner in which Plaintiff learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them, is irrelevant and unrelated to Plaintiff's claims and subject to attorney-client privilege. Plaintiffs have

agreed not to do so as to defense counsel. Not only is such testimony not related to any fact of consequence in this action, thus rendering such testimony irrelevant and inadmissible pursuant to Rules 401 and 402, but any suggestions to this effect would improperly and unjustifiably focus the trial on counsel's behavior, thus inappropriately appealing to any bias jurors may have, which is unfairly prejudicial under Rule 403. *See, e.g.*, *In re Xarelto*, 2017 WL 11718344, at *1 (E.D. La. Apr. 18, 2017) (excluding evidence of plaintiff's relationship with, and hiring of, counsel under Rule 401 and excluding evidence of counsel's advertisements "unless the information becomes relevant to the actions or inactions of the specific Plaintiff"); *Rheinfrank v. Abbott Labs., Inc.*, 2015 WL 5258858, at *11 (S.D. Ohio Sept. 10, 2015) ("Evidence about how Plaintiff retained counsel is irrelevant and therefore inadmissible."); *Kaleta v. Abbott Labs. Inc. (In re Depakote)*, 2015 WL 13951495, at *5 (S.D. Ill. Feb. 20, 2015) ("Whether Mrs. Kaleta contacted her lawyers because of a television advertisement or a friend's recommendation has nothing to do with her claims or her credibility."); *In re Yasmin & Yaz*, 2011 WL 6740391, at *16 (S.D. Ill. Dec. 22, 2011) (excluding "[a]ny comment, evidence, testimony, or inference about the date or circumstances under which Plaintiff employed her attorneys" as irrelevant).

45. Defendants cannot inject arguments regarding the consumers' damages or suggest consumers' benefitted.

This trial relates to the claims of four specific TPP subclasses only. Yet the

Court certified several more subclasses, including economic loss consumer and medical monitoring subclasses. And further, there are hundreds of consumer personal injury cases in this MDL. Defendants should not be permitted to discuss the consumers' claims, for example to argue or suggest at this upcoming trial that consumers will or will not go uncompensated, or that consumers are or are not pursuing their own damages. This would inject an irrelevant, confusing concept into the trial, leaving the jury to determine why this is being disclosed. F.R.E. 401, 403.

The same applies to any suggestion by Defendants that consumers "benefitted" from purchasing the contaminated VCDs, because that is completely irrelevant to the trial claims, and would trigger time wasting, confusing mini-trial battles into the history of what occurred, including the recalls. Fed. R. Evid. 403.

All of this said, the Court should inform the jury generally to the effect that other plaintiffs (including consumers) are pursuing other claims, but for this upcoming trial they are focused on the TPP subclasses' claims only.

46. Defendants cannot seek sympathy for big corporations targeted in litigation, or assert that they employ people in New Jersey.

Plaintiffs expect that Defendants will suggest that this case was filed to target large corporations, and try to make the jury sympathetic to the Defendants/skeptical of the Plaintiffs for filing the cases. Again, ZHP's trial counsel did exactly this in the Miami talc trial, "it can be easy to point the finger at **a big corporation like ours** because lots of people don't like corporations," "there is going to be an effort to get

you so mad at a big corporation that you turn away from the facts," "**we** employ over 40,000 people in the United States….**some of the folks that we employ right here in Miami**…" (Ex. 61, 537:8-11, 539:17-22, 543:25-544:3). These types of arguments serve no purpose other than to mislead and unduly prejudice the jury and should be precluded. F.R.E. 401, 403.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motions in limine.

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Respectfully submitted,

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